UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P O Box 1450 Alexandria, Virgima 22313-1450 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 08/28/2009

Chiron Corporation Intellectual Property PO Box 8097 Emeryville, CA 94662-8097 EXAMINER
DEVI, SARVAMANGALA J N

PAPER NUMBER

ART UNIT 1645 DATE MAILED: 08/28/2009

 APPLICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
 ATTORNEY DOCKET NO.
 CONFIRMATION NO.

 10%15,668
 07/08/2003
 Antonello Covacci
 CHIR-0337
 6533

TITLE OF INVENTION: HELICOBACTER PYLORI CAI ANTIGEN

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	11/30/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION NO THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THE APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FFE: shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

appropriate. All further indicated unless correcte maintenance fee notifica	correspondence includir ed below or directed oth	or transmitting the 1880 ig the Patent, advance of herwise in Block 1, by (rders and notification of n a) specifying a new corres	naintenance fees wi pondence address;	If be mailed to the curr and/or (b) indicating a	o snould be completed where ent correspondence address as reparate "FEE ADDRESS" for	
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.			
Chiron Corpora Intellectual Prop PO Box 8097	ation erty	V2009		Certi	ficate of Mailing or Tr		
Emeryville, CA	94662-8097					(Depositor's name)	
						(Signature)	
						(Date)	
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTORNEY DOCKET NO	. CONFIRMATION NO.	
10/615,668 TITLE OF INVENTION	07/08/2003 : HELICOBACTER PY	LORI CAI ANTIGEN	Antonello Covacci		CHIR-0337 6533		
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE	FEE TOTAL FEE(S) D	UE DATE DUE	
nonprovisional	NO	\$1510	\$300	\$0	\$1810	11/30/2009	
EXAM	INER	ART UNIT	CLASS-SUBCLASS				
DEVI, SARVAN		1645	536-023700				
1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Change of correspondence address for Change of Correspondence Address form FTO/SH22) attached. "Fee Address" indication (or "Fee Address" Indication form FTO/SB47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.			(I) the names of up to or agents OR, alternativ (2) the name of a single	e of a single firm (having as a member a ttorney or agent) and the names of up to patent attorneys or agents. If no name is a			
PLEASE NOTE: Uni recordation as set forti (A) NAME OF ASSIG	less an assignee is ident h in 37 CFR 3.11. Comp 3NEE		(B) RESIDENCE: (CITY	atent. If an assigner assignment. and STATE OR CO	OUNTRY)	e document has been filed for	
4a. The following fee(s) are submitted: Issue Fee Publication Fee (No small entity discount permitted) Advance Order - # of Copies			A check is enclosed. A check is enclosed. Payment by credit card. Form PTO-2038 is attached. Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form).				
5. Change in Entity Stat	tus (from status indicates s SMALL ENTITY statu		b. Applicant is no long				
						or the assignee or other party in	
Authorized Signature				Date			
Typed or printed name			Registration No.				
This collection of inform an application. Confident submitting the complete this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223	ation is required by 37 C tiality is governed by 35 d application form to the ons for reducing this but firginia 22313-1450. DC 13-1450.	CFR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the ONOT SEND FEES OR	on is required to obtain or r 1.14. This collection is est r depending upon the indiv e Chief Information Office COMPLETED FORMS TO	etain a benefit by the imated to take 12 m idual case. Any con rr, U.S. Patent and T D'THIS ADDRESS.	e public which is to file i inutes to complete, inclu- nments on the amount o rademark Office, U.S. I SEND TO: Commission	and by the USPTO to process) ding gathering, preparing, and f time you require to complete department of Commerce, P.O. her for Patents, P.O. Box 1450,	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P O Box 1450 Alexandria, Virgima 22313-1450 www.uspto.gov

DATE MAILED: 08/28/2009

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,668 07/08/2003		Antonello Covacci	CHIR-0337 6533	
7590 08/28/2009			EXAMINER	
Chiron Corporation			DEVI, SARVAMANGALA J N	
Intellectual Property			ART UNIT	PAPER NUMBER
PO Box 8097 Emergrille, CA 94	662-8007	1645		

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 85 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 85 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/615.668 COVACCI ET AL. Notice of Allowability Examiner Art Unit S. Devi. Ph.D. 1615 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to Applicants' amendment 4/28/09. 2. X The allowed claim(s) is/are claims 38-40, 45, 46, 48-50, 54, 57, 58, 62, 64, 65, 70 and 71, now renumbered as claims 1-3, 4, 5, 6-8, 9, 10, 11, 12, 13, 14, 15 and 16 respectively. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). b) \(\subseteq \text{Some*} \) c) \(\subseteq \text{None} \) of the: 1. Certified copies of the priority documents have been received. 2. X Certified copies of the priority documents have been received in Application No. 08471491. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: . . Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the path or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) I including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. \(\sum \) Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application Interview Summary (PTO-413), Notice of Draftperson's Patent Drawing Review (PTO-948) Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). Examiner's Amendment/Comment Paper No./Mail Date 05/06/09 4. ☐ Examiner's Comment Regarding Requirement for Deposit 8. T Examiner's Statement of Reasons for Allowance of Biological Material

9. ☐ Other

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

 Acknowledgment is made of Applicants' amendment filed 05/06/09 in response to the final Office Action mailed 02/05/09

Status of Claims

Claims 38, 49, 50, 54 and 57 have been amended via the amendment filed 05/06/09.
Claims 44 and 72 have been canceled via the amendment filed 05/06/09.
Claims 38-40, 45, 46, 48-50, 54, 57, 58, 62, 64, 65, 70 and 71 are under examination

Information Disclosure Statement

3) Acknowledgment is made of Applicants' information disclosure statement filed 10/27/08 and 05/06/09. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Rejection(s) Moot

- 4) The rejection of claims 44 and 72 made in paragraph 9 of the Office Action mailed 04/09/07, made/maintained in paragraph 20 of the Office Action mailed 11/16/07, made/maintained in paragraph 12 of the Office Action mailed 05/29/08, and made/maintained in paragraph 22 of the Office Action mailed 02/05/09 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 40 of the copending application 11/580,632, is moot in light of Applicants' cancellation of the claims.
- 5) The rejection of claim 44 made in paragraph 22 of the Office Action mailed 05/29/08 and maintained in paragraph 23 of the Office Action mailed 02/05/09under 35 U.S.C. § 102(b) as being anticipated by Covacci et al. (PNAS 90: 5791-5795, June 1993, of record), is moot in light of Applicants' cancellation of the claim.
- 6) The rejection of claim 44 made in paragraph 25 of the Office Action mailed 05/29/08 under 35 U.S.C. § 112, first paragraph, as containing new matter, is moot in light of Applicants' cancellation of the claim.

- 7) The rejection of claim 44 made in paragraph 27 of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 8) The rejection of claim 44 made in paragraph 29 of the Office Action mailed 05/29/08 under 35 U.S.C. § 102(b) as being anticipated by Peterson *et al.* (*Nature* 354: 369-373, 1991, of record) as evidenced by Stein *et al.* (*Mol. Microbiol.* 43: 971-980, 2002 Applicants' IDS), is moot in light of Applicants' cancellation of the claim.
- 9) The provisional rejection of claim 72 made in paragraph 22 of the Office Action mailed 02/05/09 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 40 of the co-pending application 11/580,632, is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

- 10) The provisional rejection of claims 38-40, 49, 50, 54, 62, 64, 65 and 71 made in paragraph 9 of the Office Action mailed 04/09/07, made/maintained in paragraph 20 of the Office Action mailed 11/16/07, made/maintained in paragraph 12 of the Office Action mailed 05/29/08 and made/maintained in paragraph 22 of the Office Action mailed 02/05/09 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 40 of the co-pending application 11/580,632, is withdrawn in accordance with MPEP 804(I)(B)(1). A potential ODP rejection would be considered during the examination of the co-pending application 11/580,632.
- 11) The rejection of claims 45, 46, 49, 50, 54, 57 and 71 made in paragraph 23 of the Office Action mailed 05/29/08 and maintained in paragraph 23 of the Office Action mailed 02/05/09 under 35 U.S.C. § 102(b) as being anticipated by Covacci et al. (PNAS 90: 5791-5795, June 1993, of record), is withdrawn in light of Applicants' amendment to the claim(s) and/or the base claim
- 12) The rejection of claims 45, 46, 49, 50, 54 and 57 made in paragraph 25 of the Office Action mailed 05/29/08 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to the claim(s) and/or the base claim.

- 13) The rejection of claims 38-40, 45, 46, 48-50, 54, 57, 58, 62, 64, 65, 70 and 71 made in paragraph 27(a) of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim(s) and/or the base claim.
- 14) The rejection of claims 39, 40, 45, 46, 48, 49, 50, 54, 57, 58, 62, 64, 65, 70 and 71 made in paragraph 27(b) of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.
- 15) The rejection of claims 45 and 46 made in paragraph 29 of the Office Action mailed 05/29/08 under 35 U.S.C. § 102(b) as being anticipated by Peterson et al. (Nature 354: 369-373, 1991, of record) as evidenced by Stein et al. (Mol. Microbiol. 43: 971-980, 2002 Applicants' IDS), is withdrawn in light of Applicants' amendment to the claim(s).

Remarks

- 16) Claims 38-40, 45, 46, 48-50, 54, 57, 58, 62, 64, 65, 70 and 71, now renumbered as claims 1-3, 4, 5, 6-8, 9, 10, 11, 12, 13, 14, 15 and 16 respectively, are allowed.
- 17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.
- 18) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.
- 19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to

Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/ Primary Examiner AU 1645

August, 2009